

K071148

DEC 22 2008

**510(k) Summary**  
**Prepared August 27, 2008**  
**Revised December 18, 2008**

**Sponsor:** Siemens Medical Solutions USA, Inc.,  
Ultrasound Division  
1230 Shorebird Way  
P.O. Box 7393  
Mountain View, California 94039-7393

**Contact Person:** Sheila W. Pickering Ph.D.  
Telephone: (650) 943 7187  
Fax: (650) 943 7053

**Submission Date:** April 18, 2008

**Device Name:** Acuson S2000 ABVS Ultrasound System

**Common Name:** Diagnostic Ultrasound System with Accessories

**Classification:**  
Regulatory Class: II  
Review Category: Tier II  
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

**A. Legally Marketed Predicate Devices**

The Acuson S2000 ABVS Ultrasound system is substantially equivalent to the Acuson S2000 ultrasound system (K072786) and the U-Systems ultrasound system..

**B. Device Description:**

The Acuson S2000 ABVS Ultrasound System has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

### **C. Intended Use**

The Modified S2000, the S2000 ABVS Ultrasound System, is intended for the following applications: General Radiology, Abdominal, Fetal, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Pediatric, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. The system supports the transducers listed in the Ultrasound Indications for Use tables, including the 14L5BV for B-mode imaging of a patient's breast using an optional automatic scanning function. The device is not intended to be used as a replacement for screening mammography.

The system also provides for the measurement of anatomical structures and analysis as provided in the original S2000 Ultrasound System, which provides information that is used by medical health care professionals for clinical diagnosis purposes.

### **D. Substantial Equivalence**

The submission device is substantially equivalent to the predicate devices with regard to both intended use and technological characteristics.

### **E. Performance Data**

The S2000 modifications are verified and validated according to the company's design control process.



DEC 16 2009

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

Ms. Shelly Pearce  
Regulatory Affairs  
Siemens Medical Solutions USA, Inc.  
Ultrasound Division  
1230 Shorebird Way  
MOUNTAIN VIEW WAY CA 94043-1344

Re: K081148  
Trade/Device Name: Acuson S2000 ABVS Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: November 21, 2008  
Received: November 26, 2008

Dear Ms. Pearce:

This letter corrects our substantially equivalent letter of December 22, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson S2000 ABVS Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2 Probe  
CW5 Probe  
EC9-4 Curved Array  
9L4 Linear Array  
14L5 Multi-D Array  
4P1 Phased Array  
6C2 Curved Array  
4C1 Curved Array  
4V1 Phased Array

10V4 Phased Array  
14L5 SP Linear Array  
7CF2 Curved Array Mechanical 3D  
9EVF4 Curved Array  
V5Ms Multiplane TEE  
18L6HD Linear Array  
8V3 Phased Array  
14L5BV Multi-D Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

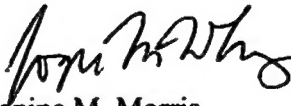
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

  
for Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

K081148

Device Name:

ACUSON S2000 ABVS Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative (Note 9)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal		P	P	P	P	P	P		BMDC	
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8, 10, 11,14
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14

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Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify) Neonatal Cardiac		P	P	P	P	P	P		BMDC	Note 3,4,6

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 6 Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 9 For example: vascular, abdominal

Note 10 Clarify VE vascular enhancement technology

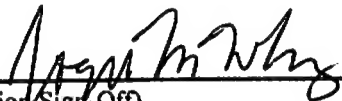
Note 11 Advanced Sieclear multi-view spatial compounding


Note 13 STIC

Note 14 eSie™ Touch elasticity imaging/FTI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K081148

Prescription Use   
(Per 21 CFR 801.109)

### Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

**14L5BV Multi-D Array Transducer for use with ACUSON S2000 ABVS**

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
<b>Ophthalmic</b>										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		N								Note 2,3,4,5,7,8,10, 11, 14
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 6 Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging

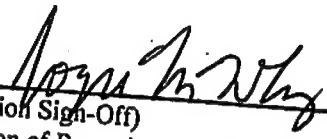
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Note 8 Power SieScape panoramic imaging  
Note 10 Clarify VE vascular enhancement technology  
Note 11 Advanced Sieclear multi-view spatial compounding  
Note 14 eSie™ Touch elasticity imaging/FTI

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)  
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and Radiological Devices  
510(k) Number K081148